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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,274	12/19/2001	David N. Herndon	D6197D	5877

7590 05/17/2005

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EXAMINER	
NGUYEN, DAVE TRONG	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,274	HERNDON ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9 and 11-15* is/are rejected.

7)☐ Claim(s) *10 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The specification has been amended, claims 5, 11, and 12 have been amended by the amendment dated July 6, 2004.

Claims 5-16, to which the following grounds of rejection, remain applicable.

The rejection under 35 USC § 112 is withdrawn because of applicant's claim amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-6, 9, 11-13 are rejected under 35 U.S.C 103(a) are rejected under 35 U.S.C. 103 as being unpatentable over Goldstein *et al.* (US Pat No. 5,962,427) taken with McDonald *et al.* (US Pat No. 6,120,799).

Goldstein *et al.* in the '427 patent directed to a DNA gene therapy method for external wound healing by using a gene activated matrix containing DNA encoding a growth factor teaches that gene activated matrix material including implants, sponges, pads, sultures, dermal patches, cadaver skin are effective matrices for enhancing the migration of wound healing and/or repair cells from surrounding tissues into a wound site that is covered by the matrices containing the therapeutic DNA (entire document, especially column 11, third paragraph, column 12, first paragraph, column 13, third paragraph, column17 bridging column 18, and column 24, last paragraph. A List of growth factors is disclosed on column 14, for example. Goldstein *et al.* does not teach the use of a cholesterol containing cationic liposome as a carrier or vector for the growth factor encoded DNA, nor does Goldstein *et al.* teach explicitly the types of wound dressings or closure materials as recited in the Markush group of the claimed invention.

However, at the time the invention was made, McDonald *et al.* (column 2 bridging column 3, column 3 bridging column 4, columns 11, 16 and 17) teaches that a therapeutically effective amount of a cholesterol containing cationic liposome is routinely employed in the art as carriers of growth factor encoded DNA so as to enhance gene expression of the delivered DNA in target cells of an external wound, see column 3

bridging column 4, column 12, lines 10-65, column 16 bridging column 17, column 19, last full paragraph, column 20, last paragraph bridging column 21.

It would have been obvious for one of ordinary skill in the art to have employed cholesterol-containing cationic liposomes as carriers or vectors of the DNA of Goldstein *et al.* so as to enhance the wound healing process of an external wound (bone rupture, ligament wound, thermal wound, or external wounds as a result of any trauma known in the prior art) in an individual. One of ordinary skill in the art would have been motivated to have employed the liposomes employed in the cited references because McDonald *et al.* is one of many prior art of record, which teaches that cholesterol-containing cationic liposomes are routinely employed in the art as effective carriers of therapeutic materials or wound enhancing growth factor encoding gene construct to enhance an efficacy of gene expression of the gene construct at its target site.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 5, 9, 11, and 15 are rejected under 35 U.S.C 103(a) are rejected under 35 U.S.C. 103 as being unpatentable over Goldstein *et al.* (US Pat No. 5,962,427) taken with McDonald *et al.* (US Pat No. 6,120,799), and further in view of Coleman (US 2003/0018984).

Goldstein *et al.* taken with McDonald *et al.* are applied here as indicated above. Goldstein *et al.* taken with McDonald *et al.* do not teach explicitly that a growth factor is IGF-I.

However, at the time the invention was made, Coleman teaches that IGF-I encoding expression vector is effective for use to treat an external wound as a result of a nerve crush, see par. 0007, page 1, and par. 0314, page 27. Cationic liposome used as a DNA carrier is also disclosed on par. 0264 of page 23.

It would also have been obvious for one of ordinary skill in the art to employ an IGF-I encoding gene construct in the wound coverage material of Goldstein *et al.* taken with McDonald *et al.* One of ordinary skill in the art would have been motivated to employ an IGF-I as a growth factor gene in the wound dressings and/or wound closure materials as wound healing agents because of the advantages as disclosed in Goldstein taken with McDonald, and because Coleman teaches that IGF-I expressing vector can be used to enhance a muscle healing in damage nerve tissues in an external wound such as a nerve crush.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 5-8, 11-14 are rejected under 35 U.S.C 103(a) are rejected under 35 U.S.C. 103 as being unpatentable over Goldstein *et al.* (US Pat No. 5,962,427) taken with McDonald *et al.* (US Pat No. 6,120,799), and further in view of anyone of Baur (US Pat No. 4,361,552), Boyce (US Pat No. 5,976,878), Kushner (US Pat No. 5,741,509), and applicant's admission over the prior art on page 29 of the specification.

Goldstein *et al.* taken with McDonald *et al.* are applied here as indicated above. Goldstein *et al.* taken with McDonald *et al.* do not teach explicitly the types of wound

dressings or closure materials as recited in the Markush group of the claimed invention, human fetal aminion.

However, Baur, Boyce, Kushner, and applicant 's admission over the prior art are exemplified references which teach that it is routine in the art at the time the invention was made for one of ordinary skill in the art to have employed wound dressing materials and/or wound closure materials including human fetal amnion on an external wound of an individual so as to enhance the wound healing of the wound.

It would also have been obvious for one of ordinary skill in the art to have further incorporated the liposomal composition of the combined cited references in a wound dressings and/or wound closure material as described in the cited references in order to enhance the wound healing process in any individual having an external wound. One of ordinary skill in the art would have been motivated to have employed the wound dressings and/or wound closure materials as wound healing agents because of the advantages as disclosed in Goldstein, Baur, Boyce, and, Kushner, and because Goldstein teaches that as long as a gene activated matrix is employed together with a DNA construct encoding a growth factor on an external wound of an individual, an enhancement of wound healing processes can be generated. One of ordinary skill in the art would have a reasons expectation of success to practice the claimed invention particularly in view of the working examples and/or disclosures of the combined cited references, and given the state of the art as a whole, as exemplified by the combined cited references.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicant's response (pages 12-14) has been considered by the examiner but is not found persuasive because of the reasons as set for in the stated rejection and following reasons. Applicant mainly asserts that McDonald *et al.* is directed to intravenous injection of cationic liposomes containing DNA encoding proteins, and that one of ordinary skill in the art would not have been motivated to combine the liposomes of McDonald *et al.* with the DNA and wound coverage materials of Goldsteins *et al.* However, on the basis of the teaching of Goldsteins *et al.* , which teaches specifically that a gene activated matrix such as a wound coverage material is effective to enhance the targeting of a solution containing a DNA construct coding for a growth factor for the treatment of an external wound, one of ordinary skill in the art would have been motivated to employ such gene activated matrix in combination with the cationic liposome/DNA complex of McDonald *et al.* By having the activated matrix containing the DNA/liposomal complex containing solution injected directly at an external wound, the matrix, as taught by Goldstein, would enhance an migration of wound healing and/or repair cells from surrounding tissues into a wound site that is covered by the matrices containing the therapeutic DNA. Given that a direction injection of a liposomal/DNA complex by itself to an external wound is far more efficient than an intravenous injection of such complex, where DNA degradation is avoid, and given a combination effect of a gene activated matrix to activate migration of repair cells to an external wound where the matrix is applied, one would have a reasonable expectation of success in applying such combination directly at an external wound.

Applicant also assert on page 12 bridging page 13 the presence of a teaching away element in McDonald, however, the fact that the liposomes are preferentially taken up by angiogenic endothelial cells in vascular tissues does not necessarily mean that liposomal carriers do not enhance an intracellular transfection of a DNA vector at a target cell located at a wound site. In fact, the as-filed application does not appear to contain any evidence to substantiate applicant's assertion that liposomal DNA vectors only are limited to use in transfecting endothelial cells. Applicant further extrapolates from the teaching of McDonald by suggesting that the liposomes somehow have the capability to target the delivery of DNA vectors to only endothelial cells. However, the assertion is not substantiated in any way by either teaching of McDonald or any other prior art. In fact, there is no evidence that by having a liposomal DNA complex enhance a preferential delivery of DNA to endothelial cells at an external wound, the DNA transfection does not effect a wound healing process in any way. Note also that the claims as pending simply recite a method of employing a combination of such liposomal/DNA complexes to at an external wound of an individual.

Applicant further asserts on page 14 that Coleman teaches away because Coleman teaches that "lipid may be useful without forming liposomes", however, the simple citation of such phase is not same as evidence showing that liposomes can not be used at all in enhancing the delivery and transfection of a DNA into cells present at a wound site.

Thus, the examiner maintains the rejections remain proper, particularly in view of the totality of the prior art of record.

Claims10 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Ram Shukla*, may be reached at **571-272-0735.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Central Fax number, which is **571-273-8300**.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

DAVE TRONG NGUYEN
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Art Unit: 1632